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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,859	07/30/2003	Gary F. Gerard	0942.5530002/RWE/HCC	6152
26111 7590 01/09/2007 STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER BURKHART, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1633	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/629,859

Applicant(s)

GERARD, GARY F.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 11-17, 19-21 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11-17, 19-21 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/20/2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections.**

The term "reduced" in claim 11 is a relative term which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. To what are the reduced levels of RNase activity of claim 11 to be compared? That is, there is no basis for determining a starting level of RNase activity to which the "reduced" activity of the claim is to be compared. Is it reduced relative to a wild-type RNase H enzyme, or a wild-type reverse transcriptase (which have RNase activity), or a mutant

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of either enzyme? The basis of comparison cannot be determined from the claim, rendering the metes and bounds of the claimed subject matter unclear.

Claim 12 recites numerous reverse transcriptase enzymes, or "derivatives" thereof. It cannot be determined how close to the original, wild-type enzymes the derivatives must be in order to anticipate the instant claim. For example, does a DNA polymerase enzyme with reverse transcriptase activity (see 35 USC § 102 rejections below) satisfy the claim limitation as a "derivative?" It cannot be determined from the instant claims, hence the metes and bounds of the claimed subject matter are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

These are new rejections.

Claims 9, 11-13, 21 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Blain et al (J. Biol. Chem., 1996). Blain et al disclose mutant Moloney Murine Leukemia Virus (M-MLV) reverse transcriptase (RT) proteins that have a reduced RNase H activity relative to the wild-type RT in the presence of Mn^{2+} (see Fig. 1 and page 1450, second column, e.g. $\Delta 5E$ and ΔC mutants). The H7 RT mutant is an RNase-null mutant (page 1449, first column, second full ¶). RT reactions using the H7 and $\Delta 5E$ mutants were performed in the presence of dNTPs

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and Mn^{2+} (page 1449, second column, first full ¶, and page 1451, second column, last ¶ to page 1452, second column, first full ¶ and Fig. 6), thus the dNTPs were in excess of Mg^{2+} because the reactions did not contain Mg^{2+} . Kits are merely a localized collection of components, and as such it is considered that the presence of all the components of the instant claims in the same tube (i.e. as in the RT assay experiments) is a "kit."

Claims 9, 11-17, 19-21 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al (Biochemistry, 1996). Myers et al teach a DNA polymerase from *T. thermophilus* (*Tth*) with reverse transcriptase activity in the presence of Mn^{2+} and dNTPs at 70 °C (page 7662, second column, third and fourth full ¶'s and Figs. 1 and 2). Thus, the dNTPs were in excess of Mg^{2+} because the reactions did not contain Mg^{2+} . The *Tth* enzyme was considered to lack RNase activity (page 7663, first column, first full ¶) and is also considered to have a "reduced" activity relative to an *E. Coli* RNase H enzyme, absent evidence to the contrary. The *Tth* enzyme is considered a "derivative" of the reverse transcriptase enzymes listed in claim 12, absent a definition of a "derivative" in the specification, and because it has reverse transcriptase activity. One RNA template used by Myers et al was amplified using a oligo dT primer ($(d(T))_{16}$, page 7662, second column, fourth full ¶ and Fig. 3) and thus was a poly A+ RNA molecule. The RT/PCR methods using the *Tth* enzyme amplified the first strand DNA, yielding a cDNA molecule (e.g. Figs. 2 to 4). Kits are merely a localized collection of components, and as such it is considered that the presence of all the components of the instant claims in the same tube (i.e. as in the RT or RT/PCR assay experiments) is a "kit."

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Conclusion

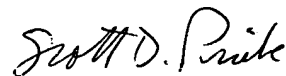
No claims are allowed. Any rejection not repeated in this Office Action is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
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SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER